

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	: : : : :	MDL No. 19-2875(RBK/KW)
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This Order Relates to all Cases

SPECIAL MASTER ORDER NO. 35

August 12, 2021

THE BACKGROUND OF THIS ORDER IS AS FOLLOWS:

Plaintiffs have filed a Motion to Compel the Production of Documents Withheld as Chinese State Secrets. (Doc. 1231.) Defendants Zhejiang Huahai Pharmaceutical Co, Ltd., Huahai U.S., Inc., Princeton Pharmaceutical Inc., and Solco Healthcare US, LLC (collectively “ZHP” or “Defendants”) have filed a Cross-Motion for a Protective Order. (Doc. 1268.) Counsel for Defendants and Plaintiffs have addressed this matter in briefs filed on the docket. (*See* Docs. 1231, 1267, 1273, and 1284.)

A. THE DOCUMENTS IN DISPUTE

The parties’ dispute concerns production of certain documents that ZHP contends are protected from disclosure by the laws of the People’s Republic of China. Specifically, at issue are fourteen (14) documents that ZHP has provided to Plaintiffs in redacted form and nine (9) documents withheld in their entirety. The

ZHP State Secret Withholding Log (annotated to show which documents have been produced in redacted form) describes the documents identified by Bates numbers as follows:

PRINBURY00142827	Minutes of a meeting dated 12 June 2017 between ZHP and Chinese Center for Drug Evaluation (CDE) regarding improving the quality of the product and register to the CDE of the China National Medical Products Administration. (REDACTED)
PRINBURY00148044	ZHP meeting minutes discussing plan to communicate with CDE regarding reply to valsartan tablet deficiency letter. (REDACTED)
ZHP02459190	Meeting minutes between ZHP and Taizhou Medical Products Administration concerning Irbesartan genotoxic impurities (REDACTED)
ZHP02557672	Document concerning an invitation for a seminar on quality control of genotoxic impurities of chemical drugs, in which the Center for Drug Evaluation (CDE) of the China National Medical Products Administration expressly required the Company to keep confidential. (REDACTED)
ZHP02604526	Minutes of meeting with National Medical Products Administration and Zhejiang Medical Products Administration concerning an inspection of a ZHP site. (REDACTED)
ZHP02605097	Minutes of a meeting minute with National Medical Products Administration concerning Irbesartan API process and nitrosamine impurities. (REDACTED)
ZHP02605629	A report on the detection of NDMA impurities in the valsartan API, prepared to send to National Medical Products Administration.
ZHP02608269	Email with the Director General of China's Food and Drug Administration of Zhejiang Province regarding the announcement of NDMA in valsartan.
ZHP02608270	Email with the Director General of China's Food And Drug Administration of Zhejiang Province regarding the announcement of NDMA in valsartan.
ZHP02608279	ZHP's response to questions raised by Zhejiang Medical Products Administration. (REDACTED)
ZHP02613610	Communications regarding meeting between ZHP and officials from CDE on the specification and exemption of products dated June 12, 2017. (REDACTED)
ZHP02615167	Summary of the reports provided to the authorities. (REDACTED)
ZHP02621763	A report intended for Zhejiang Medical Products Administration requesting guidance on data protection law. (REDACTED)
ZHP02622051	A report from Zhejiang Medical Products Administration to ZHP regarding on-site inspection. (REDACTED)

ZHP02622054	Summary of experts from National Institute for Food and Drug Control, CDE, and Zhejiang Food and Drug Administration etc. of inspections conducted between Jan. 10-Jan. 11, 2019. (REDACTED)
ZHP02622056	A report to Taizhou municipal government regarding public sentiment
ZHP02622057	A report to Taizhou municipal government regarding valsartan event
ZHP02622059	A report to Taizhou Administration for Market Regulation regarding valsartan event. (REDACTED)
ZHP02622064	A report to Taizhou municipal government regarding valsartan event. (REDACTED)
ZHP02636529	ZHP document dated Oct 22, 2018 regarding valsartan event, intended for Taizhou municipal government. (REDACTED)
ZHP02636533	A report to Zhejiang Medical Products Administration regarding progress of rectification and plan for next stage. (REDACTED)
ZHP02636534	A report to Taizhou Commerce Bureau regarding the import ban of ZHP product by EU and USA.
ZHP02649530	A report sent to National Food and Drug Administration regarding NDMA in valsartan

B. CHINESE LAW ON GUARDING STATE SECRETS

A party seeking to rely on foreign law to prevent production of discoverable information “has the burden of showing such law bars production.” *Schindler Elevator Corp. v. Otis Elevator Co.*, 657 F. Supp. 2d 525, 532 (D.N.J. 2009) (quoting *United States v. Vetco, Inc.*, 691 F.2d 1281, 1288 (9th Cir.)). ZHP relies primarily upon Articles 2 and 9(4) of the Chinese law on Guarding State Secrets to withhold the documents in question. Plaintiffs contend that the documents are not covered by this law, pointing to the March 15, 2021 Declaration of Xueyu Yang, a Chinese attorney *retained to represent ZHP* and submitted as Exhibit A to ZHP’s letter to the Court bearing the same date, Doc. 1027-1. In this declaration, Yang provides the following translation of Article 2: “State secrets shall be matters that have a *vital*

bearing on State security and national interests and, as determined according to statutory procedures, are known by people within a certain scope for a given period of time.” (*Id.* at 4; emphasis added.) Yang also provided the following translation of Article 9(4): “[t]he following matters involving State security and national interests shall be determined as State secrets if the divulgence of such matters *is likely to prejudice State security and national interests* in the fields such as political affairs, economy, national defense and foreign affairs: (4) secrets in the national economic and social development.” (*Id.*; emphasis added.)

Asserting that none of the documents in question could possibly have “*a vital bearing on State security and national interests*,” or were “*likely to prejudice State security and national interests*,” Plaintiffs contend that ZHP is unable to carry its burden to show that production of the documents would run afoul of the Chinese Law on Guarding State Secrets. *See* Brief in Supp. of Mot. to Compel, Doc. 1231-1, at 6-14. Plaintiffs thus contend that there is no need to consider whether compelled production could expose ZHP to sanctions under the Chinese Law on Guarding State Secrets. “If the party fails to produce evidence in support [of its contention that foreign law bars production], then he fails to meet his burden . . . , and the district court need not consider it.” *In re Grand Jury Proceedings (Marsoner)*, 40 F.3d 959, 964 (9th Cir. 1994).

If the translation in Yang's March, 2021 declaration correctly reflected the terms of the Law on Guarding State Secrets, Plaintiffs' position that ZHP cannot meet its burden to show that production of the documents would violate Chinese law may have merit. But ZHP does not concede that its expert's first declaration accurately reflects the Chinese Law on Guarding State Secrets. In opposing Plaintiffs' motion, ZHP submitted another Declaration from Xueyu Yang, this one dated May 21, 2021. (Doc. 1267-3.) It provides different translations of Articles 2 and 9(4). Article 2 is translated as follows: "State secrets refer to *matters which relate to the national security and interests* as determined under statutory procedures and to which access is vested in a limited scope of persons during a given period of time." (*Id.* at 23.) Thus, the limiting phrase of having a *vital bearing* on State security and national interests is eliminated. Article 9(4) is translated as follows: "The following matters which relate to the national security and interests and the leakage of which *may damage the national security and interests* in the field of politics, economy, national defense, foreign affairs, etc. shall be determined as state secrets: (4) Classified matters involved in the national economic and social

development.” (*Id.* at 24.) The revised version only requires a determination that national interests may be damaged, not that they are likely to be harmed.¹

ZHP argues that the documents in dispute fall well within the broadened definitions of state secrets, the disclosure of which may result in sanctions, including criminal prosecution. Pointing out that Plaintiffs have not countered the new Yang declaration with an affidavit from an expert in Chinese law, ZHP asserts that the new Yang declaration must be accepted as the correct translation of the Chinese Law on Guarding State Secrets and Yang’s opinions that the documents in question fall within that law also must be accepted as correct.

¹ Regarding the change in translation, the Yang May, 2021 Declaration explains:

In this Declaration, I rely on the full effect and meaning of the Chinese text of the Guarding State Secrets Law. It is noted that in my Declaration dated 15 March 2021 the English translation the Guarding State Secrets Law does not reflect accurately the meaning of the original Chinese text. For example, the English translation of Article 2 of the Guarding State Secrets Law cited in the Declaration dated 15 March 2021 states: “[s]tate secrets shall be matters that have a vital bearing on State security and national interests . . .”, whereas the Chinese text does not include the Chinese word of “vital” nor implicate the meaning of “vital” in Article 2.

(Doc. 1267-3, Yang Dec. at ¶9, n.1.)

“In determining foreign law, the court may consider any relevant material or source, including testimony, whether or not submitted by a party or admissible under the Federal Rules of Evidence.” Fed. R. Civ. P. 44.1. “In addition, courts may do their own research in order to ascertain foreign law.” *Universe Sales Co., Ltd. v. Silver Castle, Ltd.*, 182 F.3d 1036, 1038 (9th Cir. 1999).

In this case, independent research supports the conclusion that Yang’s second declaration has the correct translation of the Chinese Law on Guarding State Secrets, but not for the reasons articulated in Yang’s second declaration. The first declaration did not incorrectly translate the Chinese law. Instead, it translated an incorrect version of the law.

According to one commentator, the original Law on Guarding State Secrets, enacted in 1989, defined “state secrets” as “matters that have a vital bearing on state security and national interests.” See Sigrid U. Jernudd, Comment, *China, State Secrets, and the Case of Xue Feng: The Implication for International Trade*, 12 CHI. J. INT’L L. 309, 317 (2011). The commentator goes on to explain that the law was amended in 2010, with the definition of “state secrets” being “broadened somewhat, as the language requiring a ‘vital bearing’ . . . [was] removed so that the clause simply reads ‘matters that relate to state security and national interests.’” *Id.* As explained by another scholar:

China has strong data protection laws, including the Law of the People's Republic of China on Guarding State Secrets (Chinese State

Secrets Law), which was first passed in 1989 and revised in 2010. The Chinese State Secrets Law broadly defines state secrets to include “matters that relate to state security and national interests,” a statement that leaves much ambiguity and uncertainty regarding what types of data may be collected and transferred out of the country during an investigation.

Lucian E. Dervan, *International White Collar Crime and the Globalization of Internal Investigations*, 39 Fordham Urb. L.J. 361, 376–77 (2011). Professor Dervan also notes that “[t]he pre-2010 Chinese State Secrets Law covered ‘matters that have a vital bearing on state security and national interests.’ The 2010 amendment removed the terms ‘vital bearing’ and, therefore, made the provision arguably broader than [previously].” *Id.* at 389. An online translation of Article 2 and 9 also supports the conclusion that the current Law on Guarding State Secrets no longer requires that the information in question have a “vital bearing” on state security or national interests, but simply relate to those concerns, and that the disclosure of the information *could* harm the state’s security and national interests, not that such damage be likely. See <https://www.cecc.gov/resources/legal-provisions/law-on-the-protection-of-state-secrets-cecc-partial-translation-and> (Last visited Aug. 12, 2021).²

² The translation on this site is as follows:

Article 2. State secrets are matters that relate to state security and national interests, are specified in accordance with legally defined

These sources of information compel the conclusion that the translation in the second Yang declaration is correct, and that Chinese law precludes disclosure of documents that merely relate to state security and national interests. In view of the fact that ZHP has submitted evidence that the documents in question fall within the

procedures, and the knowledge of which is restricted to a defined scope of personnel within a defined period of time.

...

Article 9. The following matters that relate to state security and national interests, if leaked could harm the state's security and national interests in the areas of politics, economy, national defense, foreign relations, among others, shall be defined as a state secret:

- (1) secret matters in major policy decisions on state affairs;
- (2) secret matters in the building of national defense and in the activities of the armed forces;
- (3) secret matters in diplomatic activities and in activities related to foreign countries as well as secret matters to be maintained as commitments to foreign countries;
- (4) secret matters in national economic and social development;
- (5) secret matters in science and technology;
- (6) secret matters in activities for safeguarding state security and the investigation of criminal offences; and
- (7) other secret matters that are determined by the department administering and managing the protection of state secrets.

Secrets of political parties that conform with the requirements of the above provisions shall be state secrets.

broad ambit of the Chinese Law on Guarding State Secrets,³ and Plaintiffs have not tendered conflicting evidence, I find that the production of the documents in question may violate Chinese law.

C. COMITY ANALYSIS

However, even where foreign law, known as a “blocking statute,” prohibits disclosure of requested information, United States courts retain the power to “order a party subject to its jurisdiction to produce evidence even though the act of production may violate that statute.” *Societe Nationale Industrielle Aerospatiale v. U.S. Dist. Court for S. Dist. of Iowa*, 482 U.S. 522, 544 n.29 (1987); *see also Munoz v. China Expert Tech., Inc.*, 07 CIV. 10531 AKH, 2011 WL 5346323, at *1 (S.D.N.Y. Nov. 7, 2011) (“China’s state secrecy and other related laws . . . have broad sweep and can preclude disclosure of a host of nebulously defined categories of information. . . . And thus they are viewed with some skepticism in U.S. courts.”). As explained in *Aerospatiale*, “neither the discovery order nor the blocking statute can have the same omnipresent effect that it would have in a world of only one sovereign. The blocking statute . . . is relevant . . . only to the extent that its terms

³ ZHP relies on the May, 2021 Yang Declaration, which asserts that she has personally reviewed the 23 documents. Yang concludes only that “the 23 documents at issue *may* implicate state secrecy information and therefore should not be produced by ZHP without prior consent given by the relevant PRC government organs.” (Yang Decl. at ¶22, Doc. 1267-3; emphasis added). It is unclear whether government approval has been sought.

and its enforcement identify the nature of the sovereign interests in nondisclosure of specific kinds of material.” 482 U.S. at 544. The Court also endorsed the view that “when a state has jurisdiction to prescribe and its courts have jurisdiction to adjudicate, adjudication should (subject to generally applicable rules of evidence) take place on the basis of the best information available.” *Id.* (internal quotation marks and citations omitted.).

In determining whether to order production of information arguably falling under a foreign blocking statute the following factors should be considered: (1) the importance to the litigation of the documents requested; (2) the degree of specificity of the request; (3) whether the information originated in the United States; (4) the availability of alternative means of securing the information; (5) the extent to which noncompliance with the request would undermine important interests of the United States, or compliance with the request would undermine important interests of the state where the information is located; (6) the extent and nature of the hardship that enforcement would impose upon the foreign entity; and (7) the good faith of the party opposing discovery. *Strauss v. Credit Lyonnais, S.A.*, 242 F.R.D. 199, 210 (E.D.N.Y. 2007). Where the weight of the factors favors disclosure, production of the documents should be ordered. *See Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468, 1475 (9th Cir. 1992).

Each of these factors will be considered for each document in dispute. This analysis, however, is constrained by the limited description of the documents provided on ZHP's Amended State Secrets Privilege Log, as supplemented by the transcribed meet and confer session conducted by the parties on March 26, 2021.⁴

1. Importance of the Discovery

The first factor the Court must consider is the importance of the foreign discovery requested. As the Ninth Circuit explained in *Richmark*, courts are hesitant to order discovery that would override foreign laws where the outcome of the litigation “does not stand or fall on the present discovery order.” 959 F.2d at 1475. “This factor calls on the court to consider the degree to which the information sought is more than merely relevant under the broad test generally for evaluating discovery requests.” *In re Activision Blizzard, Inc.*, 86 A.3d 531, 544 (Del. Ch. 2014). If, however, the evidence is “directly relevant,” compelling disclosure is favored. *Id.* (citing *Vetco*, 691 F.2d at 1290).

In support of their Motion, Plaintiffs argue that they “need the 23 documents at issue in order to ensure a full and complete record of ZHP's liability in this case.”

⁴ The parties were directed to meet and confer with a court reporter present to attempt to reduce the number of disputes concerning the documents withheld on the basis of Chinese state secret laws. The parties have submitted the transcript of their meet and confer session in connection with their respective motions. *See* Doc. 1267-5. Counsel are to be commended for the professionalism exhibited in conducting this session, which included Ms. Yang, and they also are to be commended for their work in reducing the number of documents in dispute.

(Doc. 1273 at 9.) They point out that the documents involve the “primary defendants whose actions, decisions, and related communications lie at the heart of this proceeding.” *In re Activision Blizzard, Inc.*, 86 A.3d at 544. In opposition, ZHP argues that Plaintiffs have not shown that any of the documents at issue are “crucial” or “vital” to this litigation. (Doc. 1267 at 12.) It does appear, however, that the documents are “directly relevant” to Plaintiffs’ claims. In this regard, it is noteworthy that 14 of the 23 documents in dispute have been produced in part, thus suggesting a recognition that the documents are indeed relevant, and the descriptions on the documents withheld in their entirety indicate their relevance to this proceeding. Accordingly, this factor weighs in favor of compelling disclosure.

2. Degree of Specificity

Next, the Court must consider the degree of specificity of the requests for foreign discovery. In support of their Motion, Plaintiffs argue that their requests for production are “Court ordered,” and “the product of an extensive meet and confer process as well as significant briefing and oral argument.” (Doc. 1273 at 10.) ZHP, in opposition, argues that Plaintiffs’ requests are broad and overreaching, requesting “more than ninety-five categories of documents from the ZHP Parties, comprehensively covering their operations potentially relating to valsartan.” (Doc. 1267 at 15.)

Plaintiffs' requests are not the generalized and burdensome searches contemplated by *Aerospatiale* and *Richmark*. Indeed, even seeking a "great deal of information" does not favor non-disclosure where the information is directed at narrowly-defined issues, as is the case here. *Richmark*, 959 F.2d at 1475. Given the fact that the document requests were the subject of extensive negotiations and close judicial supervision, this factor weighs in favor of disclosure.

3. Country of Origination

The third factor concerns whether the information at issue originated in the United States or abroad. This factor weighs in favor of nondisclosure where all of the requested information sought and the people involved in assembling it are located in a foreign country. *See Richmark*, 959 F.2d at 1475. Here, the parties do not dispute that the twenty-three (23) documents at issue did not originate in the United States, and all of the custodians responsible for maintaining the information are located in China or were located there during the time the information was collected. This factor weighs against disclosure.

4. Availability of Alternative Means of Securing Information

Another pertinent factor is whether there are alternative means to obtain the requested information. The alternative means must be "substantially equivalent" to the requested discovery. *Id.* (citing *Vetco*, 691 F.2d at 1290). In support of their Motion, Plaintiffs argue that, to the extent the information in the twenty-three (23)

documents are deemed Chinese state secrets, Plaintiffs do not have an alternative means of obtaining that information. (Doc. 1273 at 11.) ZHP, in opposition, argues that Plaintiffs may obtain the information contained in ZHP's State Secret Review Log elsewhere, and in fact, Plaintiffs have already obtained the relevant information, if any, contained in these documents. (Doc. 1267 at 18.) While it may be that *the information* contained in the documents may have otherwise been produced to Plaintiffs, there can be no dispute that they do not have access to the documents in question and no dispute that the only way to verify that the information contained in the documents at issue has already been provided to Plaintiffs is to examine the documents. Accordingly, this factor weighs in favor of disclosure.

5. Balance of National Interests

This factor looks to the sovereign interests of the United States as compared with those of the foreign country. The Ninth Circuit has described this factor as the most important. *Richmark*, 959 F.2d at 1476. The interests of each nation in requiring or prohibiting disclosure must be assessed to determine whether disclosure would “affect important substantive policies or interests” of either the United States or the other nation. *Id.* (citation omitted). The United States has a “substantial” interest in “vindicating the rights of American plaintiffs,” *Richmark*, 959 F.2d at 1477, and an “overriding interest in the ‘just, speedy, and inexpensive determination’ of litigation in [its] courts,” *Aerospatiale*, 482 U.S. at 543. Assessing the strength

of China's interests includes consideration of "'expressions of interest by the foreign state,' 'the significance of disclosure in the regulation . . . of the activity in question,' and 'indications of the foreign state's concern for confidentiality prior to the controversy.'" *Id.* at 1476.

Three of the documents in question were created by an organ of the Chinese government: ZHP0255672 (concerning an invitation for a meeting on quality control of genotoxic impurities of chemical drugs); ZHP02622051 (a report from the Zhejiang Medical Products Administration regarding an onsite inspection); and ZHP02622054 (a summary prepared by the Center for Drug Evaluation, the National Institute for Food and Drug Control, and the Zhejiang Food and Drug Administration). China's interests in confidentiality would appear to be greatest with respect to its own documents. As recognized by Judge Shira Scheindlin, "[o]rdering the production of the non-public regulatory documents of a foreign government may infringe the sovereignty of the foreign state and violate principles of international comity to a far greater extent than the ordered production" of information created by a private entity. *Wultz v. Bank of China Ltd.*, 910 F. Supp. 2d 548, 556 (S.D.N.Y. 2012). Indeed, the China National Products Administration expressly required confidentiality with respect to ZHP0255672. As to these three documents, the interests of China preponderate and weigh against compelling disclosure.

As to the other documents, however, there is no expression from the Chinese government that disclosure of the documents would imperil state security or any national interest. Nor has there been any expression of concern from the Chinese government during the many months that this dispute involving the Chinese Law on Guarding State Secrets has been pending. Under these circumstances, as to the other 20 documents in question, the United States' interests preponderate.

6. Hardship on Foreign Entity

The extent and nature of the hardship that the discovery request is likely to have on the foreign entity is another factor to consider. While criminal and civil penalties may be imposed on individuals who violate Chinese state secrecy laws, there is great uncertainty as to whether production of these documents would violate Chinese state secrecy laws or prompt any prosecution. Yang's opinion on this point was extremely equivocal. Accordingly, this factor favors disclosure.

7. Good Faith of the Party Resisting Discovery

The final factor to balance in determining whether to compel production of documents arguably covered by a foreign blocking statute is the resisting party's good faith. In this case, ZHP has demonstrated good faith. From a production totaling several hundred thousand documents, it has withheld only a handful of documents in their entirety on the basis of the Law on Guarding State Secrets, and

relatively few documents have been redacted on the basis of that law. This factor weighs against compelled disclosure.

D. CONCLUSION

The relevant *Aerospatiale* and *Richmark* factors plainly weigh in favor of disclosure, with the exception of the three documents generated by a Chinese government agency. Accordingly, ZHP will be directed to produce all but the following three documents: ZHP0255672, ZHP02622051, and ZHP02622054. ZHP's motion for a protective order will be denied, with the exception of those three documents.

NOW, THEREFORE, IT IS HEREBY ORDERED THAT:

1. Plaintiffs' Motion to Compel (Doc. 1231) is **GRANTED IN PART AND DENIED IN PART**. Within seven (7) days of the date of this Order, ZHP shall produce all documents that are the subject of Plaintiffs' Motion to Compel, along with all documents listed as duplicates of these documents on its log of documents withheld as Chinese state secrets, with the exception of the following three documents and any duplicates of the following three documents: ZHP0255672, ZHP02622051, and ZHP02622054.
2. ZHP's Motion for Protective Order (Doc. 1268) is **GRANTED IN PART**. ZHP need not produce the following three documents and any

duplicates of the following three documents: ZHP0255672, ZHP02622051, and ZHP02622054. In all other respects, ZHP's Motion for Protective Order is **DENIED**.

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master